## Remarks

Claims 1, 2, 4-13, and 15-25 were pending. By way of this response, claims 1 and 23 have been amended. Support for the amendments to the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 1, 2, 4-13, and 15-25 are currently pending.

### Rejection Under 35 U.S.C. § 112

Claims 18, 19, 24, and 25 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for the recitation of "at least" since it is the Examiner's opinion that the claims are indefinite for failing to set forth an upper limit.

Applicant respectfully traverses the rejection.

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph (MPEP § 2173.04).

Claims 18 and 24 recite "at least one additional agonist", claim 19 recites "at least one additional fatty acid component", and claim 25 recites "at least two fatty acid components".

Applicant submits that the scope of the subject matter embraced by claims 18, 19, 24, and 25 is clear. For example, the subject matter of these four claims is directed to compositions that comprise two or more agonists, or two or more fatty acid components. There is no ambiguity or indefiniteness as to the subject matter being claimed.

In view of the above, applicant submits that claims 18, 19, 24, and 25 are definite under 35 U.S.C. § 112, second paragraph. Therefore, applicant respectfully requests that the rejection of claims 18, 19, 24, and 25 under this statutory provision be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 1, 2, 4-6, 15-17, and 21 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Neumann. Claims 1, 2, 5, 6. 9-13, 15-17, and 20-21 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by DeSantis Jr. et al.

Although applicant disagrees with the rejections, to advance the prosecution of the above-identified application, claims 1 and 23 have been amended. Claims 1 and 23, and the claims dependent therefrom, recite that the composition includes a quinoxaline component and a fatty acid component present as an ion pair complex. Applicant respectfully traverses the above-noted rejections as they relate to the amended claims.

Applicant submits that the prior art fails to disclose or teach compositions comprising a complex of a quinoxaline

component and a fatty acid component which results in enhanced movement of the quinoxaline component across lipid membranes. Moreover, the prior art does not teach, disclose, or even suggest any composition comprising an ion pair complex of a quinoxaline component and a fatty acid component, let alone such a composition recited in the presently rejected claims. Accordingly, applicant submits that the presently rejected claims, that is claims 1, 2, 4-6, 9-13, and 15-17, and 20-21, are not anticipated by the prior art under 35 U.S.C. § 102.

Applicant acknowledges that the Examiner has withdrawn the inherency rejection. Applicant therefore concludes that the rejection of the claims under 35 U.S.C. § 102 is due to the Examiner's opinion that each reference alone expressly discloses all the limitations recited in the present claims.

However, the Examiner's rejection specifically states that Neumann teaches the "use of an alpha-2 adrenergic agonist and a fatty acid component in a pharmaceutical formulation" (page 2 of the Office Action) and that DeSantis et al. "teach the use of clonidine with a fatty acid prostaglandin in a pharmaceutical formulation for the treatment of glaucoma" (page 2 of the Office Action).

Importantly, the Examiner fails to state or identify any portion of Neumann or DeSantis et al., or any other prior art reference, that discloses an alpha-2-adrenergic agonist and a fatty acid component present as a complex in a composition. Since the Examiner has specifically described what Neumann and DeSantis et al. disclose, as indicated above and on page 2 of the Office Action, it is clear that the Examiner cannot identify

any portion in either reference which discloses a composition comprising a quinoxaline component and a fatty acid component present as a complex, let alone as an ion pair complex, as recited in the present claims. Thus, applicant submits that the Examiner has no proper basis for the present anticipation rejections. As stated in earlier responses, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Emphasis added; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Because the prior art, including Neumann and DeSantis et al., does not describe, either expressly or inherently, a composition comprising a quinoxaline component and a fatty acid component present as an ion pair complex, the claims cannot be properly rejected under 35 U.S.C. § 102.

Again, applicant respectfully requests the Examiner to precisely indicate where (by column and line number) each and every element of the pending claims is expressly disclosed in Neumann and DeSantis Jr. et al. Specifically, applicant requests the Examiner to indicate where either reference discloses a complex between a quinoxaline component and a fatty acid component and, in addition, that such a complex is an ion pair complex. Absent such a showing, applicant submits that the present rejections cannot be properly maintained, and must be withdrawn.

In addition, applicant submits that neither Neumann nor DeSantis Jr. et al., taken alone or in any combination, provides even a suggestion to modify the reference or references to obtain the claimed invention.

In view of the above, applicant submits that the present claims 1, 2, 4-6, 9-13, 15-17, and 20-21 are not anticipated by, and are unobvious from and patentable over, Neumann and DeSantis Jr. et al., taken alone or in any combination, under 35 U.S.C. §§ 102 and 103.

Rejections Under 35 U.S.C. § 103

Claims 7, 8, 22, and 23 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 00/44355. Applicant traverses the rejections.

It is the Examiner's position that, based on the disclosure of WO 00/44355, it would have been obvious to a person skilled in the art to substitute one fatty acid or alpha-2-adrenergic agonist for another, absent of evidence to the contrary. (November 5, 2002 Office Action, page 3). Applicant respectfully disagrees and respectfully submits that the Examiner's position is not the proper legal standard on which an obviousness rejection is made under 35 U.S.C. § 103.

As applicant has indicated previously, WO 00/44355 actually **teaches away** from the presently claimed compositions since WO 00/44355 is directed to low solubility salts. In contrast, the presently claimed compositions are directed to complexes including a fatty acid component that is effective to enhance movement of a quinoxaline component across a lipid membrane. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing In re Gurley, 31 USPQ2d 1131,

(Fed. Cir. 1994)). Accordingly, because WO 00/44355 is directed to low solubility salts, and because the present invention is directed to compositions containing a quinoxaline component with enhanced movement properties, applicant submits that one of ordinary skill in the art would not be motivated by WO 00/44355 to modify the teachings of WO 00/44355 to obtain the present invention.

In addition, as stated in the above-identified application, and as recited in the present claims, the present compositions provide the unexpected advantage of the reduction of at least one undesirable side effect when the composition is administered to a patient, relative to a substantially identical composition without a fatty acid component. Applicant submits that WO 00/44355 does not disclose, teach, or even suggest the present claims, and does not provide any motivation to one of ordinary skill in the art to extend the different teachings of WO 00/44355 for the purpose of obtaining the present compositions and the substantial and unexpected advantages of such compositions, e.g., reduced side effects, achieved by applicant.

Furthermore, even if a motivation were present to modify WO 00/44355, which applicant does not concede, the modification would fail to disclose, teach, or even suggest all of the claim limitations, including for example, any complex between a quinoxaline component and a fatty acid component, let alone an ion pair complex between a quinoxaline component and a fatty acid component, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 7, 8, 22, and 23, are unobvious from and patentable over WO 00/44355 under 35 U.S.C. § 103.

In addition, applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims satisfy 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1, 2, 4-13, and 15-25 are allowable. Applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 5/12/04

Respectfully submitted,

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